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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/095,536	06/10/98	KINK J	OPHD-03282

HM12/0829

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EXAMINER	
HAMUD,F	
ART UNIT	**PAPER NUMBER**
1647	12

DATE MAILED: 08/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary

Application No.	Applicant(s)
09/095,536	John A. Kink
Examiner	**Group Art Unit**
Fozia Hamud	1647

☒ Responsive to communication(s) filed on *May 22, 2000* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-23* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-23* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The request filed on 05/22/00 in Paper No.10, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/095,536 is acceptable and a CPA has been established. An action on the CPA follows.

2. The amendment filed on 05/22/ in Paper No.11 has been entered.

New claims 19-23 have been added in Paper No.11 filed on 05/22/00. Thus claims 1-23 are pending and under consideration.

3. The following previous objections and rejections are withdrawn in light of Applicants amendments filed in Paper No:11 filed on 05/22/00:

(I) The rejection of claims 1-3, 7-15 made under U.S.C. § 103 as being unpatentable over Starnes et al. (12/92) and Doherty et al (09/92).

(II) The rejection of claims 1, 3-6 and 16-18 made under U.S.C. § 103 as being unpatentable over Starnes et al. (12/92) and Doherty et al (09/92) in view of Emery et al (U.S. Patent 5,420,253).

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Applicant's arguments filed in Paper Nos.11 filed on 05/22/00, have been fully considered and were deemed persuasive. New issues are stated below.

Claim Rejections - 35 U.S.C. § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6a. Claims 1-23, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising purified antibodies directed to TNF-α, IL-6 and/or IFN-γ, and a method of treating symptoms of sepsis or septic shock by administering said composition, is not enabling for compositions comprising antibodies to "all" TNF in combination with antibodies to IL-6 and/or interferon gamma, or a method of treating "all possible" diseases by administering said composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1 and 19 are overly broad for reciting "a composition comprising purified antibodies directed to TNF..." and claim 7 is overly broad for reciting " a method of treatment, comprising providing a mammal a therapeutic preparation comprising anti-TNF ...". The specification is only enabling for a composition comprising purified antibodies directed to TNF-α, in combination with antibodies against IL-6 and/or interferon-gamma and a method of treating sepsis using said composition, because the specification, using a murine model of endotoxic shock, demonstrates that antibodies directed to TNF-α alone, or in combination with antibodies to IL-6 and/or antibodies to interferon-gamma neutralize the lethal effect of endotoxin *in vivo*, (see Examples 2, 3, and 5 on pages 9-15 and tables 1, 2 and 4). Thus the instant specification is non-enabling for a composition comprising antibodies to "all" TNF or a method of treating "all possible" diseases by administering said composition, because TNF-α differs structurally, chemically and physically from TNF-β, and while the specification shows that antibodies against TNF-α alone or in combination with antibodies

directed to IL-6 and/or interferon gamma are able to neutralize the lethal effect of endotoxin *in vivo*, the instant specification is silent with respect to antibodies directed to TNF-β and sepsis. Furthermore, TNF-α and TNF-β genes are differently regulated at the transcriptional level. The criteria set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims, is the basis for determining undue extermination. In the instant application, claim 7 and claims that depend from it, are overly broad, for not specifying the disease to be treated, using the instantly claimed composition. Furthermore, the skilled artisan would not be able to predict if antibodies directed to TNF-β, alone or in combination with antibodies to IL-6 and/or interferon gamma would be effective against septic shock, as encompassed by the scope of the claims 1, 7 and 19, and there is no guidance provided in the specification with respect to antibodies directed to TNF-β. With respect to claim 7, which does not specify which disease to treat, it would constitute undue experimentation to determine which disease or diseases to treat utilizing a composition comprising purified antibodies directed to TNF in combination with antibodies directed to IL-6 and/or interferon gamma in a safe and effective manner. Furthermore, there are no working examples in the instant case, demonstrating that antibodies directed to TNF-β, alone or in combination with antibodies to IL-6 and/or interferon gamma, are effective against sepsis, neither are there any working examples demonstrating that antibodies directed to TNF-α in combination with antibodies directed to IL-6

and/or interferon gamma are effective against "all" possible diseases. Therefore, because of the breadth of the claims, the unpredictability of the field, the lack of guidance provided and the lack of working examples, the instant specification is not enabling for compositions comprising antibodies to "all" TNF in combination with antibodies to IL-6 and/or interferon gamma, or a method of treating "all possible" diseases by administering said composition, but is only enabling for a composition comprising purified antibodies directed to TNF-α, IL-6 and/or IFN-γ, and a method of treating symptoms of sepsis or septic shock by administering said composition.

Claims 2-6, 8-18 and 20-23 are rejected under 112, first paragraph, insofar as they depend on claims 1, 7 and 19 for the limitations set forth directly above.

Conclusion

7. No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8896. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
August 21, 2000

Gary L. Kunz
GARY L. KUNZ
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